

1/40

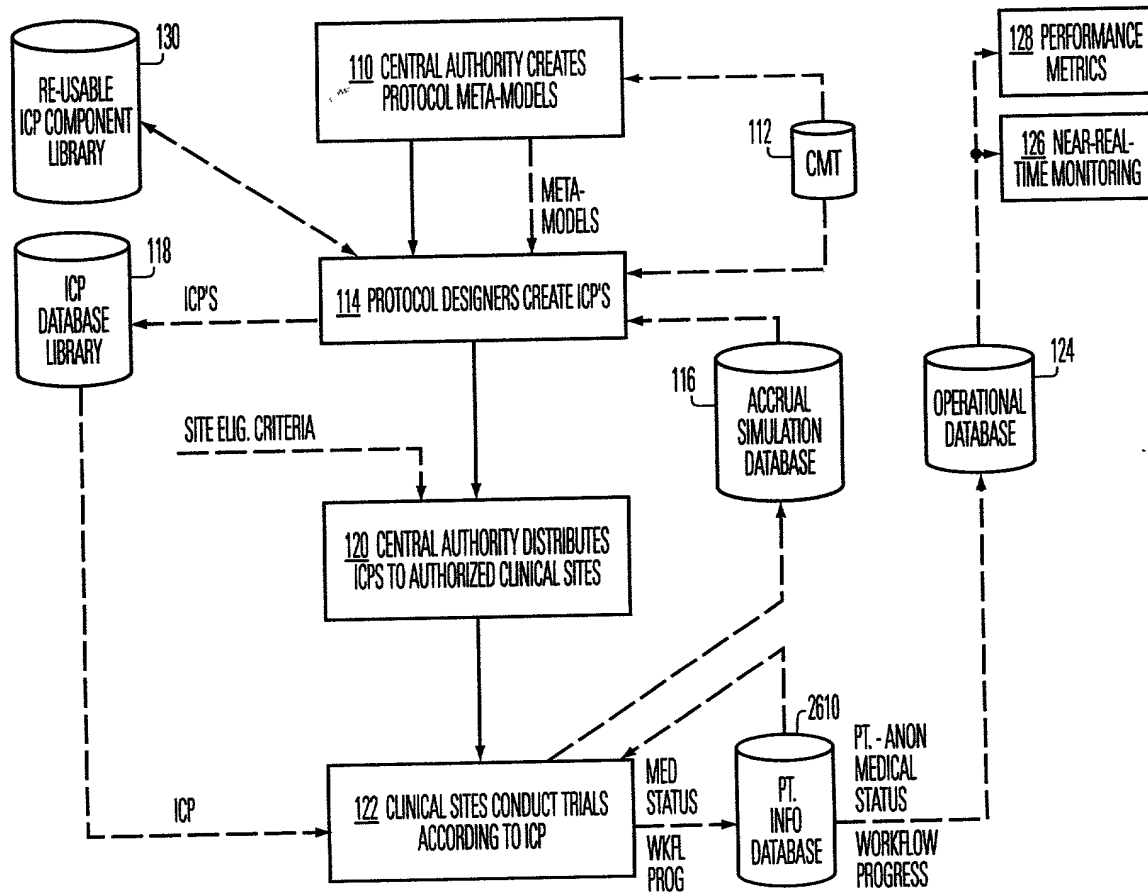


FIG. 1

204050" 28TD660

2/40

cancer_protocols_INSTANCE_00039 [Instance of Cancer_Clinical_Protocol]	
Label	Version
CALGB 49802	mgk
Title	Authors
Phase III Study of Adriamycin/Taxotere vs Adriamycin/Cytosan for the Adjuvant Treatment of Node Positive or High Risk Node Negative Breast Cancer	M.G. Public
Clinical Algorithm	Reference
CALGB 49802 Level 1	MUSC PRN web page
Context Reference	
Entry Criteria (1 values)	
Protocol Name	Inclusion List
CALGB 49802	<ul style="list-style-type: none">Historically or cytologically confirmed invasive breast cancer1-3 histologically involved axillary lymph nodesNo evidence of metastatic disease (M0)Absolute neutrophil count of at least 1,500/mm³Platelet count of at least 100,000/mm³Left ventricular ejection fraction at rest at least 45% by MUGABilirubin no greater than 1.2 times upper limit of normal (ULN)Age 18-70Effective contraception required of fertile womenNo prior chemotherapyNo prior radiotherapyNo concurrent estrogen therapy
Clinical State Name	
Exclusion List	
<ul style="list-style-type: none">Tumor of any size with direct extension to chest wall or skin (T4)Patient is pregnant or nursing	

FIG. 2

2040CE0"28T02660

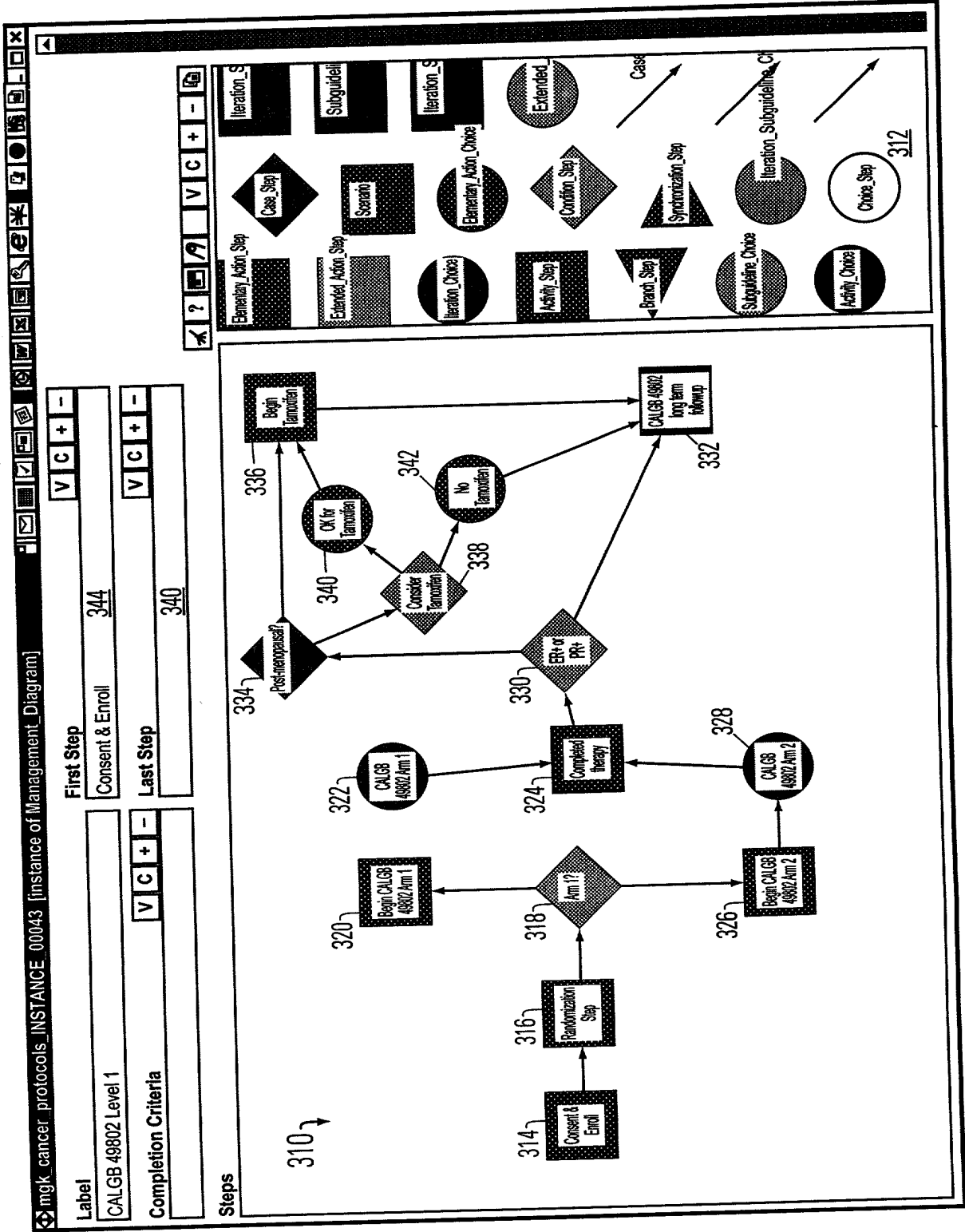


FIG. 3

4/40

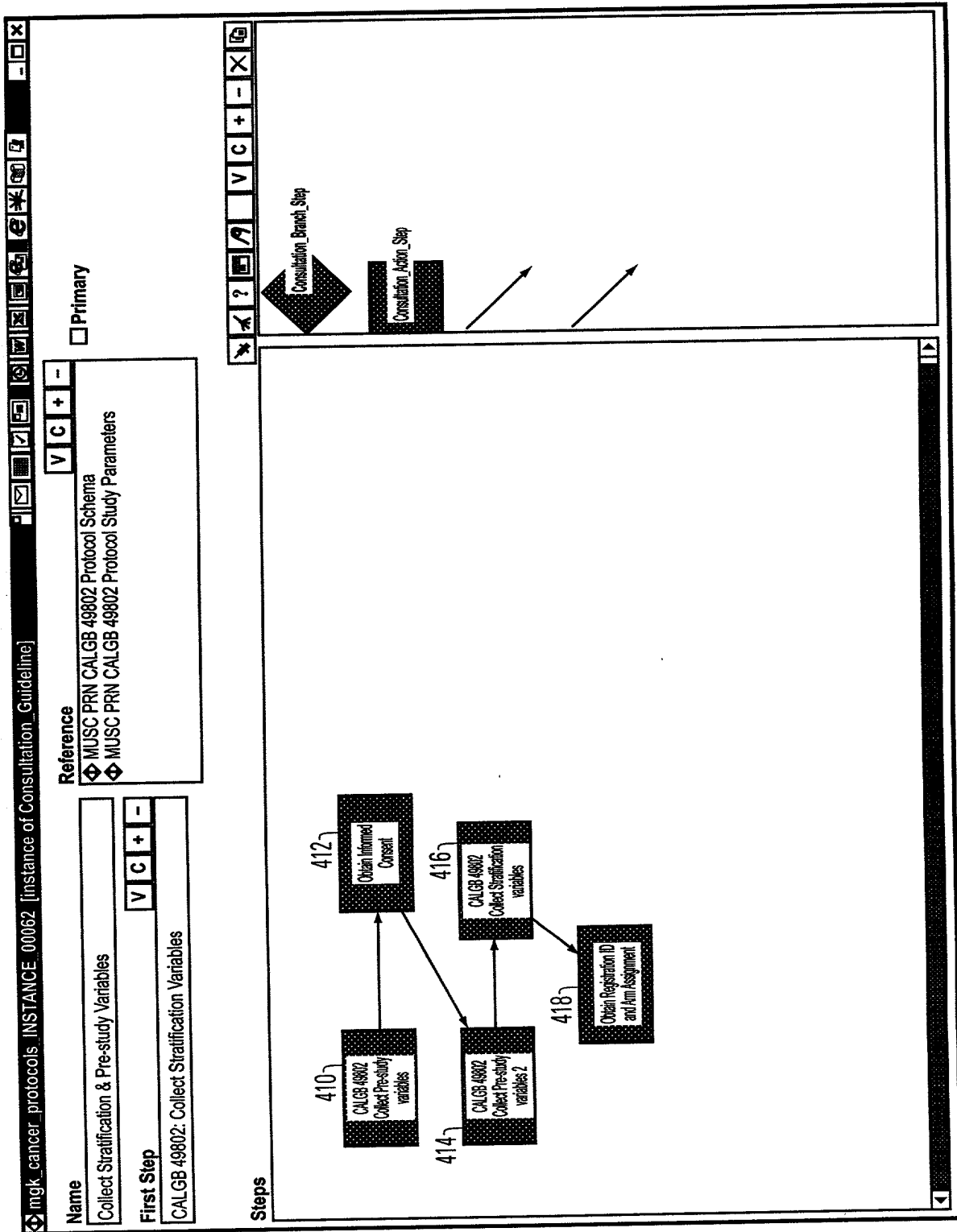


FIG. 4

5/40

mgk_cancer_protocols_INSTANCE_00063 [instance of Consultation Act...]

Label		mgk_cancer_protocols_INSTANCE_00063 [instance of Consultation Act...]	
CALGB 49802: Collect Stratification Variables		<ul style="list-style-type: none">◆ Evaluate lymph node status◆ Evaluate menopausal status◆ Evaluate estrogen receptor status◆ Evaluate progesterone receptor status	
Followed By	V C + -		
Rule In	V C + -	References	V C + -
Rule Out	V C + -		

FIG. 5

6/40

2040E0"28T04660

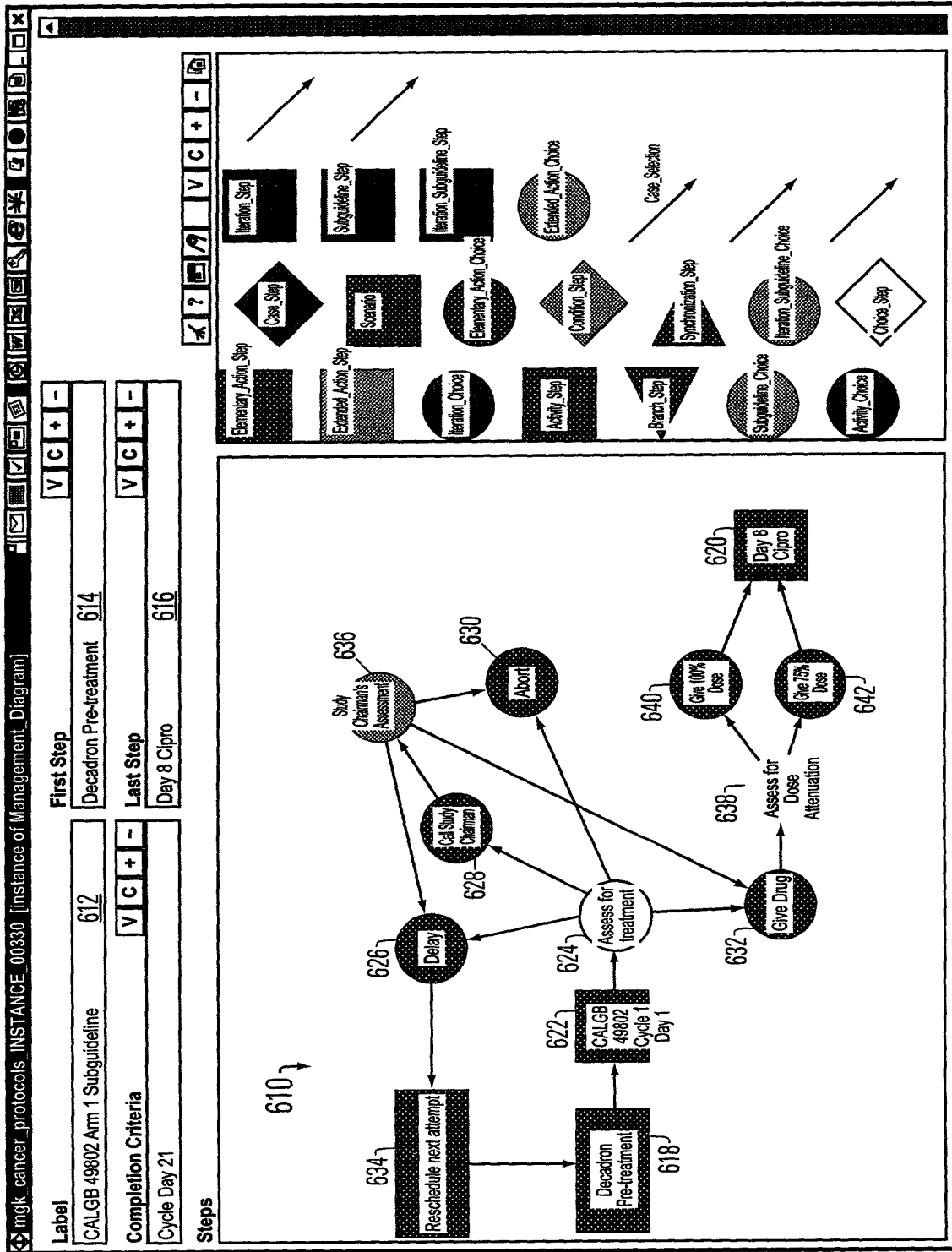


FIG. 6

7/40

2044050" 2870.660

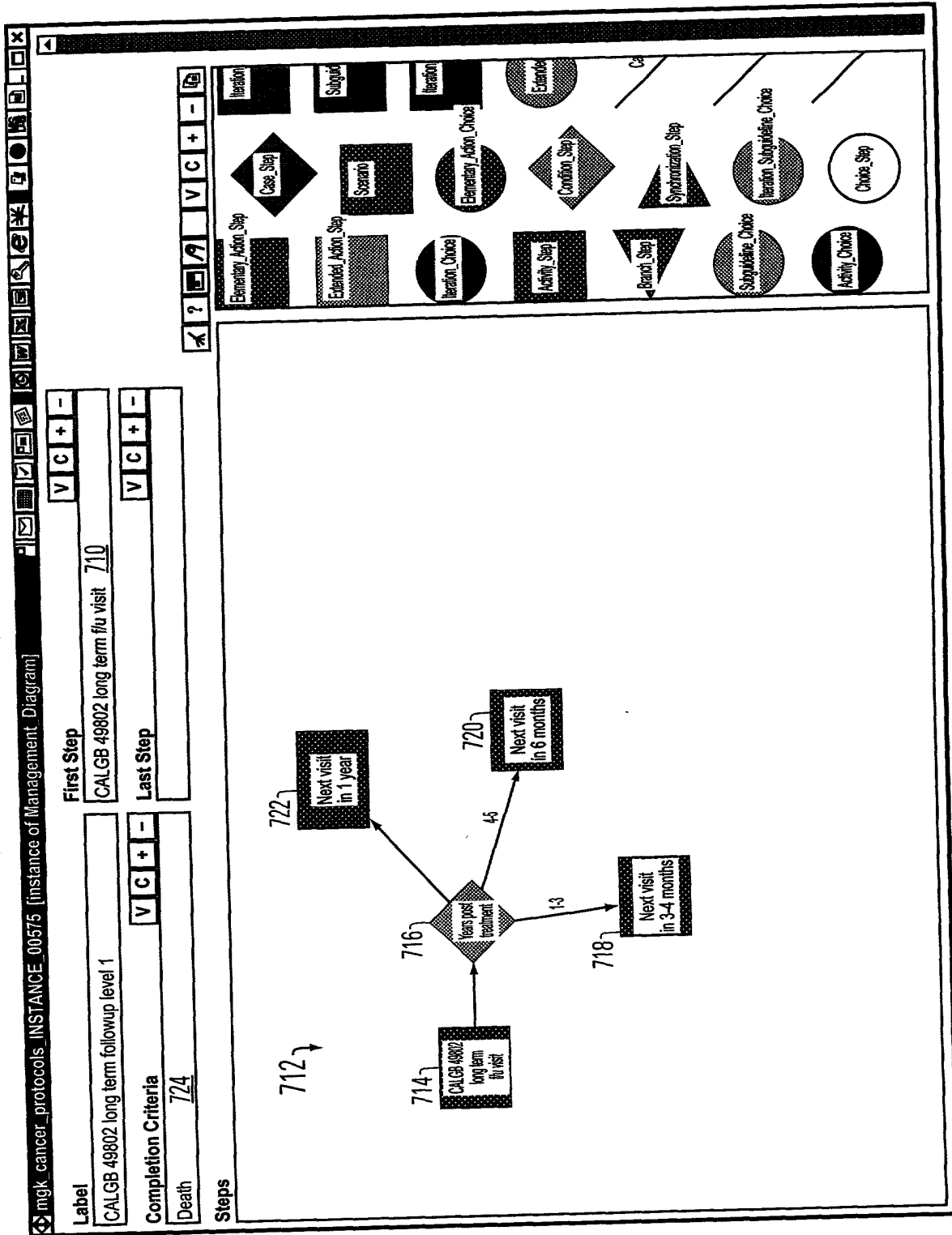


FIG. 7

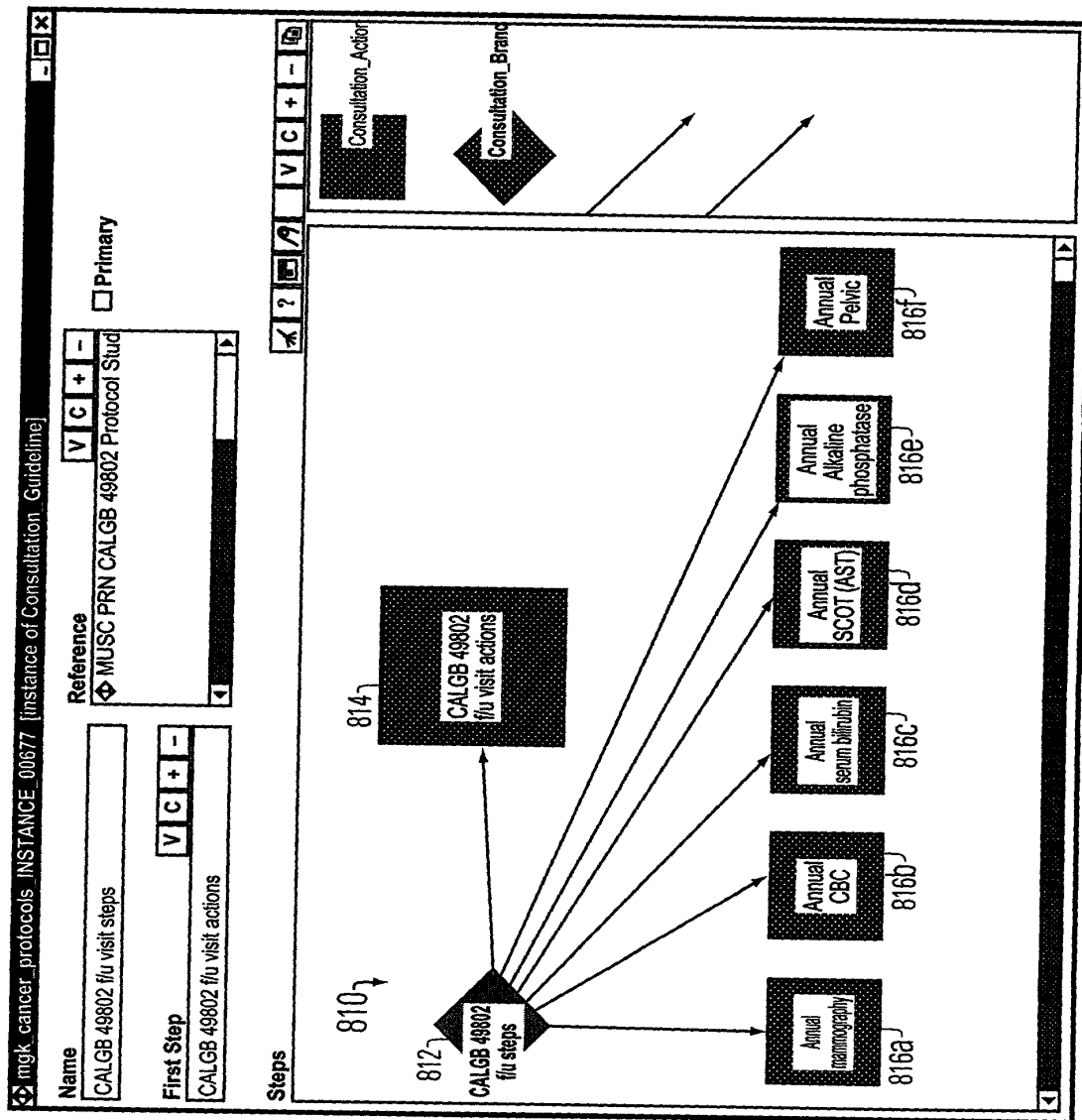


FIG. 8

9/40

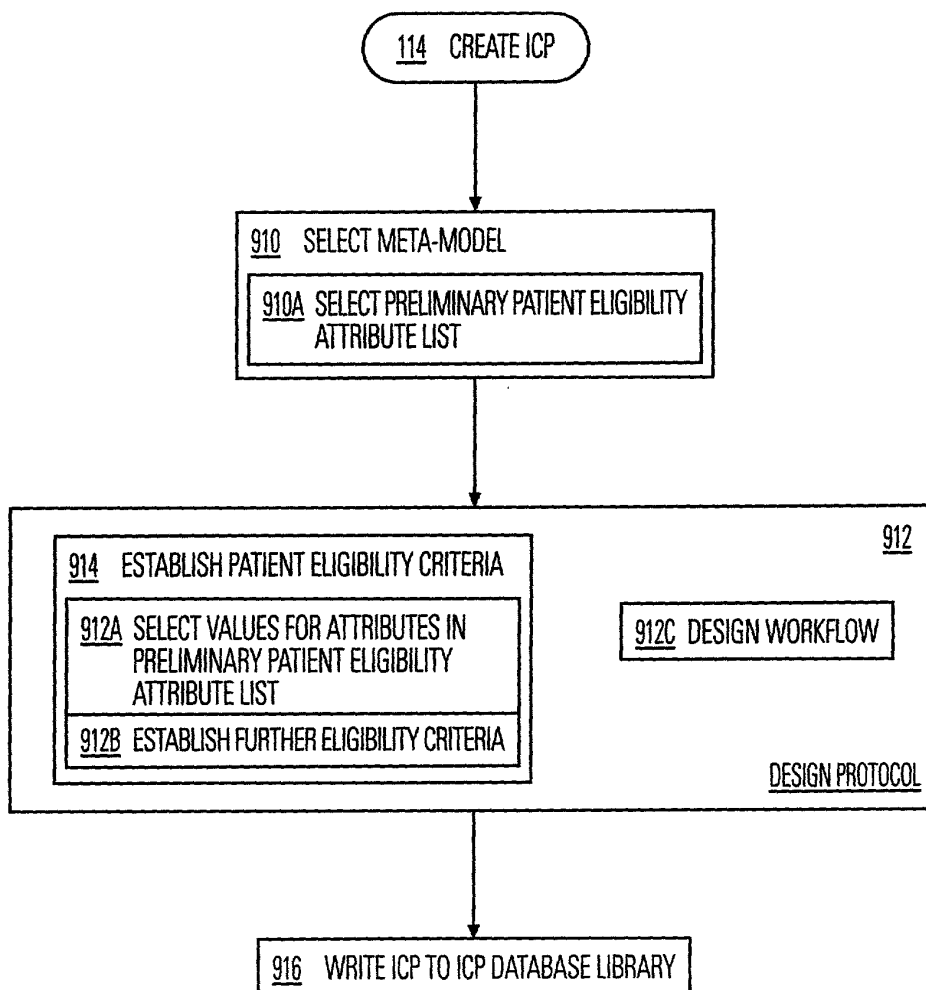


FIG. 9

10/40

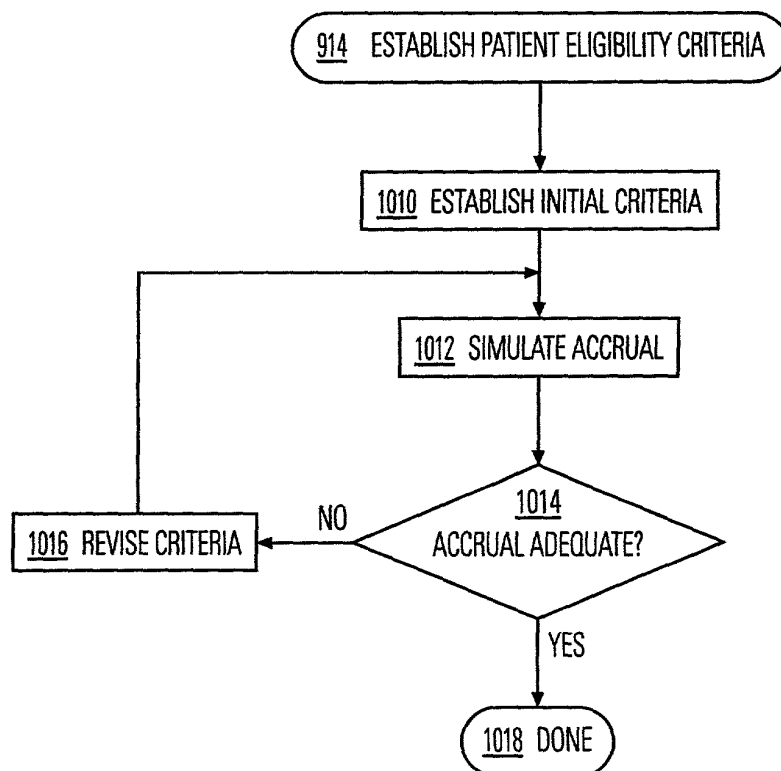


FIG. 10

11/40

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.pprj]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass V C X

ThingA
SYSTEM-CLASS^A
Diagram_Entity
Date
ProtocolElement^A — 1112
EligibilityCriteriaSet — 1124
EligibilityCriterion
PatientManagementTask — 1130
Protocol — 1116
ProtocolSchemaDiagram^M — 1132
Visit — 1128
VisitToVisitTransition^M
DiseaseArea
Disease^A — 1150
WeightedPath — 1152
ApplicationArea
VisitCycle — 1154
DiseaseQualifiers^A
ModelVersion — 1110

Protocol (Instance of rdfs:Class)

Name Protocol

Constraints V C + -

Role Concrete

Documentation
The document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol also usually gives the background and

Template Slots

Name	Type	Cardinality	Default	Other Facets
protocolSchemaDiagram	Instance	Single		classes={ProtocolSchemaDiagram}
protocolTitle	String	Single		
quickScreenCriterion	Symbol	Single		
rdfs:isDefinedBy	Instance	Single		values={Prostate Cancer, Colorectal Cancer, Breast Cancer}
rdfs:seeAlso	Instance	Single		1122 classes={URI, rdfs:Resource}
resource uri	Instance	Single		classes={URI}
shortDescription	String	Single		
siteAccrualTarget	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		
sponsor	String	Single		
sponsorAccrualTarget	String	Single		
studyChair	String	Single		
trialPhase	String	Single		values={Phase I, Phase II, Phase IV, Phase I, Phase III}
trialStatus	Symbol	Single		values={On Hold, Terminated, Active}

Rdfs:isDefinedBy V C + -

Rdfs:seeAlso V C + -

Resource Uri 66 V + -

Superclasses
ProtocolElement^A

1118

1114

FIG. 11

12/40

FastTrack Protocol_INSTANCE_00212 [instance of Protocol]

ProtocolTitle	Version
A Phase III Study of Paclitaxel via Weekly 1-Hour Infusion v	Update #1
ProtocolIdentifier	VersionDate
CALGB 9840	December 15
OfficialSourceDocument	EligibilityCriteriaSet
http://pm.musc.edu/research/protocol/deptmed/divhonc/br	<input type="checkbox"/> V <input type="checkbox"/> C <input type="checkbox"/> + <input type="checkbox"/> -
ShortDescription	<input checked="" type="checkbox"/> CALGB 9840 Eligibility Criteria 1212
CALGB 9840	
StudyChair	
Andrew D. Seidman, M.D.	
Sponsor	LongDescription
CALGB	
QuickScreenCriterion	
Breast Cancer 1210	
ProtocolObjectives	
To compare "standard" (S) paclitaxel at 175 mg/m2 via 3-hour infusion every 3 weeks to "dose-dense" (DD) paclitaxel at 80 mg/m2 via 1-hour infusion every week	
TrialStatus	AccrualStatus
Active	Open for accrual
TrialPhase	TrialType
Phase III	Cooperative-group
	FirstVisit
	<input type="checkbox"/> V <input type="checkbox"/> C <input type="checkbox"/> + <input type="checkbox"/> -
	Screening Visit
	ProtocolSchemaDiagram
	<input type="checkbox"/> V <input type="checkbox"/> C <input type="checkbox"/> + <input type="checkbox"/> -
	CALGB 9840 Schema 1214

FIG. 12

13/40

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppr]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass V C X

φ: THING^A

- ⊖: SYSTEM-CLASS^A
- ⊖: Diagram_Entity
- ⊖: Date
- ⊖: ProtocolElement^A — 1112
- ⊖: EligibilityCriteriaSet — 1124
- ⊖: EligibilityCriterion
- ⊖: PatientManagementTask — 1130
- ⊖: Protocol — 1116
- ⊖: ProtocolSchemaDiagram^M — 1132
- ⊖: Visit — 1128
- ⊖: VisitToVisitTransition^M
- ⊖: DiseaseArea
- ⊖: Arm
- ⊖: WeightedPath
- ⊖: ApplicationArea
- ⊖: VisitCycle
- ⊖: Disease^A
- ⊖: DiseaseQualifiers^A
- ⊖: ModelVersion

1126

1110

⊖: EligibilityCriteriaSet (Instance of rdfs:Class)

Name: EligibilityCriteriaSet V C + -

Role: Concrete

Documentation: A criterion which determines whether or not a subject is eligible to participate in the study. A criterion is either an inclusion criterion that prospective subjects must meet to be eligible, or an

Constraints: V C + -

Template Slots

Name	Type	Cardinality	Default	Other Facets
exclusionCriteria	Instance	Multiple		classes={EligibilityCriterion}
inclusionCriteria	Instance	Multiple		classes={EligibilityCriterion}
longDescription	String	Single		
rdfs:isDefinedBy	Instance	Single		classes={URI, rdfs:Resource}
rdfs:seeAlso	Instance	Single		classes={URI, rdfs:Resource}
resource uri	Instance	Single		classes={URI}
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

Rdfs:isDefinedBy V C + -

Rdfs:seeAlso V C + -

Resource Uri 66 1 1 V C + -

1310

Superclasses

- ⊖: ProtocolElement^A

FIG. 13

14/40

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppr]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass V C X

① THINGA
② SYSTEM-CLASS^A
③ Diagram_Entity
④ Date
⑤ ProtocolElement^A — 1112
⑥ EligibilityCriteriaSet — 1124
⑦ EligibilityCriteria
⑧ PatientManagementTask — 1130
⑨ Protocol — 1116
⑩ ProtocolSchemaDiagram^M — 1132
⑪ Visit — 1128
⑫ VisitToVisitTransition^M
⑬ DiseaseArea
⑭ WeightedPath
⑮ ApplicationArea
⑯ VisitCycle
⑰ Disease^A
⑱ DiseaseQualifiers^A
⑲ ModelVersion

① EligibilityCriteria (Instance of rdfs:Class)

Name
EligibilityCriteria

Role
Concrete

Constraints V C + -

Documentation
A criterion which determines whether or not a subject is eligible to participate in the study. A criterion is either an inclusion criterion that prospective subjects must meet to be eligible, or an

Template Slots

Name	Type	Cardinality	Default	Other Facets
longDescription	String	Single		
rdfs:isDefinedBy	Instance	Single		classes={URL,rdfs:Resource}
rdfs:seeAlso	Instance	Single		classes={URL,rdfs:Resource}
resource uri	Instance	Single		classes={URI}
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

Rdfs:isDefinedBy V C + -

Rdfs:seeAlso V C + -

Resource Uri 66 ± V + -

1410

FIG. 14

15/40

FastTrack Protocol_INSTANCE_00074 [instance of EligibilityCriteriaSet]

ShortDescription
CALGB 9840 Eligibility Criteria

InclusionCriteria ☐ ☐ ☐ ☐ ☐

- ☐ Female
- ☐ Breast adenocarcinoma that is inoperable, recurrent, or metastatic
- ☐ More than 4 weeks since last chemotherapy
- ☐ More than 6 weeks since treatment with nitrosureas, melphalan, o
- ☐ More than 4 weeks since last hormonal therapy OR tumor measur
- ☐ Age >= 18
- ☐ Measurable disease
- ☐ Granulocytes >= 1,500 / ul
- ☐ Platelet count >= 100,000 / ul
- ☐ Creatinine <= 2.0 mg/dl
- ☐ Bilirubin within institutional normal limits
- ☐ SGOT (AST) <= 3X upper limits of normal
- ☐ Greater than 2 weeks from prior surgery

ExclusionCriteria ☐ ☐ ☐ ☐ ☐

- ☐ More than 1 prior chemotherapy regimens for metastatic or locally
- ☐ CNS metastases if untreated or symptomatic—1510
- ☐ Prior taxane for metastatic or locally-advanced breast cancer
- ☐ Prior taxane in adjuvant setting where patient remained disease fr
- ☐ Leptomeningeal carcinoma

LongDescription

SiteLongDescription

SiteShortDescription

Rdfs:isDefinedBy ☐ ☐ ☐ ☐ ☐

Rdfs:seeAlso ☐ ☐ ☐ ☐ ☐

Resource Uri ☐ ☐ ☐ ☐ ☐

FIG. 15

16/40

FastTrack Protocol INSTANCE 00073 [instance of EligibilityCriterion]

ShortDescription
CNS metastases if untreated or symptomatic
LongDescription
Patients with central nervous system metastases are eligible only if the patient has completed cranial irradiation at least 6 months prior, is currently asymptomatic, and is not currently receiving corticosteroids for this condition.
SiteLongDescription
SiteShortDescription

FIG. 16

17/40

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppr]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass V C X

Thing^A

SYSTEM-CLASS^A

Diagram_Entity

Date

ProtocolElement^A — 1112

EligibilityCriteriaSet — 1124

EligibilityCriterion

PatientManagementTask — 1130

Protocol — 1116

ProtocolSchemaDiagram^M — 1132

Visit — 1128

VisitToVisitTransition^M

DiseaseArea

Arm

WeightedPath

ApplicationArea

VisitCycle

Disease^A

DiseaseQualifiers^A

ModelVersion

1110

Visit (Instance of rdfs:Class)

Name

Visit

Constraints

V C + -

Documentation

An actual encounter between the provider and a patient on study. A number of possible visits are associated with a study (Protocol).

Role

Concrete

Template Slots

Name	Type	Cardinality	Default	Other Facets
dataManagementTasks — 1716	Instance	Multiple		classes={ManagementTask}
longDescription	String	Single		
patientManagementTasks	Instance	Multiple		classes={ManagementTask}
possibleVisitTransitions — 1714	Instance	Multiple		classes={VisitToVisitTransition}
rdfs:isDefinedBy	Instance	Single		classes={URI, rdfs:Resource}
rdfs:seeAlso	Instance	Single		classes={URI, rdfs:Resource}
resource uri	Instance	Single		classes={URI}
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

Rdfs:isDefinedBy

V C + -

Rdfs:seeAlso

V C + -

Resource Uri

64 1710

Superclasses

ProtocolElement^A

FIG. 17

18/40

FastTrack Protocol INSTANCE 00014 [Instance of Visit]

ShortDescription

Arm A Treatment Visit

PossibleVisitTransitions

Arm A Treatment to Arm A Treatment Retry #1 1818

Arm A Treatment to Long Term Followup 1818

Arm A Treatment Visit to Arm A Treatment Visit 1810

DataManagementTasks

Submit Form C-116 1818

Submit Form C-118 1818

Submit Form C-080

Submit Form C-344 + Form C-080 (*)

Submit Form C-344 + Form C-272 (*)

Submit Form C-113 (*)

Submit Form C-260 (*)

Submit Form C-300 (*)

PatientManagementTasks

Confirm granulocytes $\geq 15000 / \mu l$

Confirm no G-CSF given in past 24 hours

Give Dexamethosone 10 mg IV, 30 minutes

Give Diphenhydramine 50 mg IV, 30 minutes

Give Cimetidine 300 mg IV, 30 minutes

Give anti-emetics (*)

Give Arm A Paclitaxel treatment 1816

Give G-CSF (*)

Evaluate Patient Response

Schedule next visit

LongDescription

Arm A of the CALG 9840 consists of treatment with Paclitaxel 175 mg/m² administered as a 3 hour infusion intravenously every three weeks. One cycle is equivalent to one infusion. Treatment cycles will be repeated every 21 days as long as the patient has stable or responding disease. Granulocyte count must be $\geq 1500 / \mu l$ and platelet count must be $\geq 100,000 / \mu l$ on day 1 of each cycle. Patients should receive a minimum of two cycles of therapy, unless there is rapid disease progression ($>50\%$ increase in product of bi-dimensional measurements).

SiteLongDescription

SiteShortDescription

FIG. 18

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.pprj]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass V C X

THING^A

SYSTEM-CLASS^A

Diagram_Entity

Date

ProtocolElement^A - 1112

EligibilityCriteriaSet - 1124

EligibilityCriterion

PatientManagementTask - 1130

Protocol - 1116

ProtocolSchemaDiagram^M - 1132

Visit - 1128

VisitToVisitTransition^M

DiseaseArea

Ann

WeightedPath

ApplicationArea

VisitCycle

Disease^A

DiseaseQualifiers^A

ModelVersion

ManagementTask (Instance of rdfs:Class)

Name

ManagementTask

Constraints

V C + -

Documentation

A task related to this visit. Includes:
checks that tasks prior to this visit
occurred, oks that tasks performed
during this visit were done, or
reminders for tasks to perform before

Role

Concrete

Template Slots

Name	Type	Cardinality	Default	Other Facets
longDescription	Symbol	Single		values={Medium,High,Low}
longDescription	String	Single		
rdfs:isDefinedBy	Instance	Single		classes={URI,rdfs:Resource}
rdfs:seeAlso	Instance	Single		classes={URI,rdfs:Resource}
resource uri	Instance	Single		classes={URI}
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

Superclasses

+ -

ProtocolElement^A

Rdfs:isDefinedBy

V C + -

Rdfs:seeAlso

V C + -

Resource Uri

64 1 1 V + -

1910

FIG. 19

20/40

FastTrack Protocol_INSTANCE_00206 [Instance of ManagementTask]

ShortDescription

Give Arm A Paclitaxel treatment

LongDescription

Give Paclitaxel 175 mg/m² IV, 3hours. This treatment is given to patients in Arm A of the CALGB 9840 protocol. It is given once every 3 weeks. One cycle is equivalent to one infusion. Granulocyte count must be $\geq 1500/\mu\text{l}$ and platelet count must be $\geq 100,000/\mu\text{l}$ on day 1 of each cycle in order to proceed with the Paclitaxel infusion. Patients must receive the pre-medication prior to Paclitaxel infusion. If either the granulocyte or platelet count are not adequate, do not continue with treatment. Patients should receive a minimum of 2 cycles unless there is rapid disease progression.

Expected toxicities:

Dose Modifications:

SiteLongDescription

FIG. 20

21/40

FastTrack Protocol_INSTANCE_00196 [instance of ManagementTask]

ShortDescription
Submit Form C-116

LongDescription
Submit CALGB Advanced Breast Cancer Followup-form (C-116) every two cycles while on protocol therapy, at 6 & 12 months after end of treatment, at disease progression or initiation of non-protocol therapy.

SiteLongDescription

SiteShortDescription

FIG. 21

22/40

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.pprj]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass V C X

Diagram showing relationships between classes:

- THING^A
 - SYSTEM-CLASS^A
 - Diagram_Entity
 - Date
 - ProtocolElement^A - 1112
 - EligibilityCriteriaSet - 1124
 - EligibilityCriterion
 - PatientManagementTask - 1130
 - Protocol - 1116
 - ProtocolSchemaDiagram^M - 1132
 - Visit - 1128
 - VisitToVisitTransition^M - 2210
 - DiseaseArea
 - Arm
 - WeightedPath
 - ApplicationArea
 - VisitCycle
 - Disease^A
 - DiseaseQualifiers^A
 - ModelVersion

VisitToVisitTransition (Instance of Connector_Metaclass)

Name: VisitToVisitTransition

Role: Concrete

Constraints: V C + -

Documentation: A one-way link between a source visit (first_object) and a target visit (second_object). The inherited descriptions specify guidance about when/how/why to make this transition.

Template Slots

| Name | Type | Cardinality | Default | Other Facets |
|------------------------------|----------|-------------|---------|-----------------------------|
| first_object - 2214 | Instance | Single | | classes={Visit} |
| longDescription | String | Single | | |
| maximumRelativeTime - 2218 | String | Single | | |
| minimumRelativeTime - 2220 | String | Single | | |
| preferredRelativeTime - 2222 | String | Single | | |
| rdfs:isDefinedBy | Instance | Single | | classes={URI,rdfs:Resource} |
| rdfs:seeAlso | Instance | Single | | classes={URI,rdfs:Resource} |
| resource uri | Instance | Single | | classes={URI} |
| second_object - 2216 | Instance | Single | | classes={Visit} |
| shortDescription | String | Single | | |
| siteLongDescription | String | Single | | |
| siteShortDescription | String | Single | | |

First Object Slot Pointer: V C + -

Rdfs:isDefinedBy: V C + -

Rdfs:seeAlso: V C + -

Second Object Slot Pointer: V C + -

2212

FIG. 22

23/40

1818

FastTrack Protocol_INSTANCE_00023 [instance of VisitToVisit Transition]

| | | |
|--|---------|------------------------------|
| ShortDescription | | PreferredRelativeTime |
| Arm A Treatment to Arm A Treatment Retry # | | 7 |
| First Object | V C + - | MaximumRelativeTime |
| Arm A Treatment Visit | | 7 |
| Second Object | V C + - | MinimumRelativeTime |
| Arm A Treatment Retry #1 | | 7 |

LongDescription

If either granulocyte or platelet count are not adequate, blood counts should be repeated weekly and treatment should be instituted when there has been hematologic recovery. Patients receiving G-CSF are not eligible for re-treatment unless they have been off G-CSF for a minimum of 24 hours.

SiteLongDescription

☐ IsPreferredTransition 2310

SiteShortDescription

FIG. 23

24/40

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppt]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass V C X

φ:THING^A

- φ:SYSTEM-CLASS^A
- φ:Diagram_Entity
- φ:Date
- φ:ProtocolElement^A—1112
- φ:EligibilityCriteriaSet —1124
- φ:EligibilityCriterion
- φ:PatientManagementTask —1130
- φ:Protocol —1116
- φ:ProtocolSchemaDiagram —1132
- φ:Visit —1128
- φ:VisitToVisitTransition^M—2210
- φ:DiseaseArea
- φ:Ami
- φ:WeightedPath
- φ:ApplicationArea
- φ:VisitCycle
- φ:Disease^A
- φ:DiseaseQualifiers^A
- φ:ModelVersion

1110

© ProtocolSchemaDiagram (Instance of Network_Metaclass)

Name: ProtocolSchemaDiagram

Role: Concrete

Constraints: V C + -

Documentation: The ProtocolSchemaDiagram is the part of the protocol which details the design of the trial. A protocol schema's first visit is always at least one screening visit, which is assumed

Template Slots

| Name | Type | Cardinality | Default | Other Facets |
|-----------------------|----------|-------------|---------|----------------------------------|
| connectors —2410 | Instance | Multiple | | classes={VisitToVisitTransition} |
| diagramNodes —2412 | Instance | Multiple | | classes={Visit} |
| last_divider_location | Integer | Single | | |
| layout_information | Instance | Multiple | | classes={ObjectLocation} |
| longDescription | String | Single | | |
| main_panel_height | Integer | Single | | |
| main_panel_width | Integer | Single | | |
| rdfs:isDefinedBy | Instance | Single | | classes={URI,rdfs:Resource} |
| rdfs:seeAlso | Instance | Single | | classes={URI,rdfs:Resource} |
| resource uri | String | Single | | classes={URI} |
| shortDescription | String | Single | | |
| siteLongDescription | String | Single | | |
| siteShortDescription | String | Single | | |

Node Slot: V C + -

diagramNodes

Rdfs:isDefinedBy: V C + -

Rdfs:seeAlso: V C + -

Superclasses: + -

ProtocolElement^A

FIG. 24

25/40

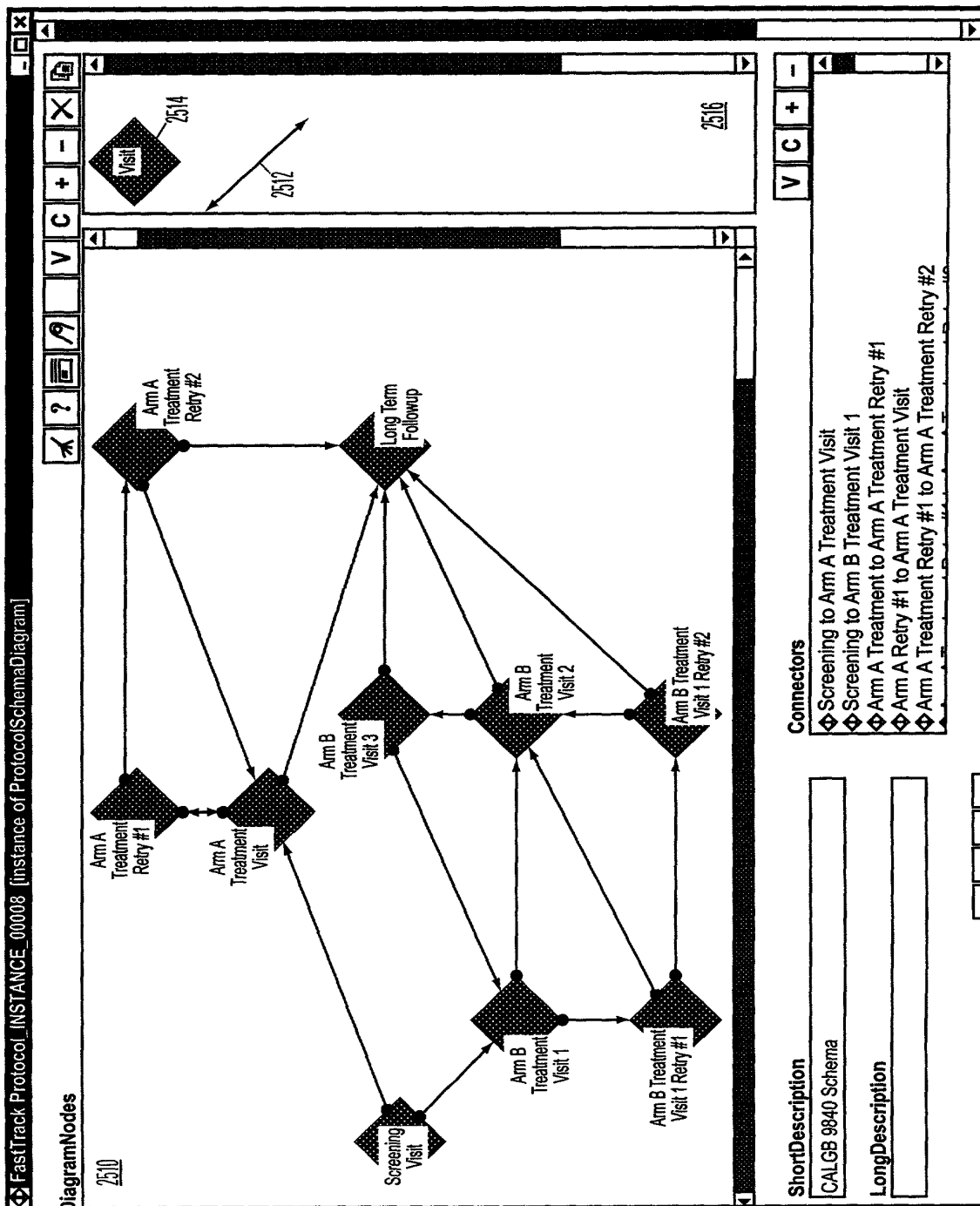


FIG. 25

26/40

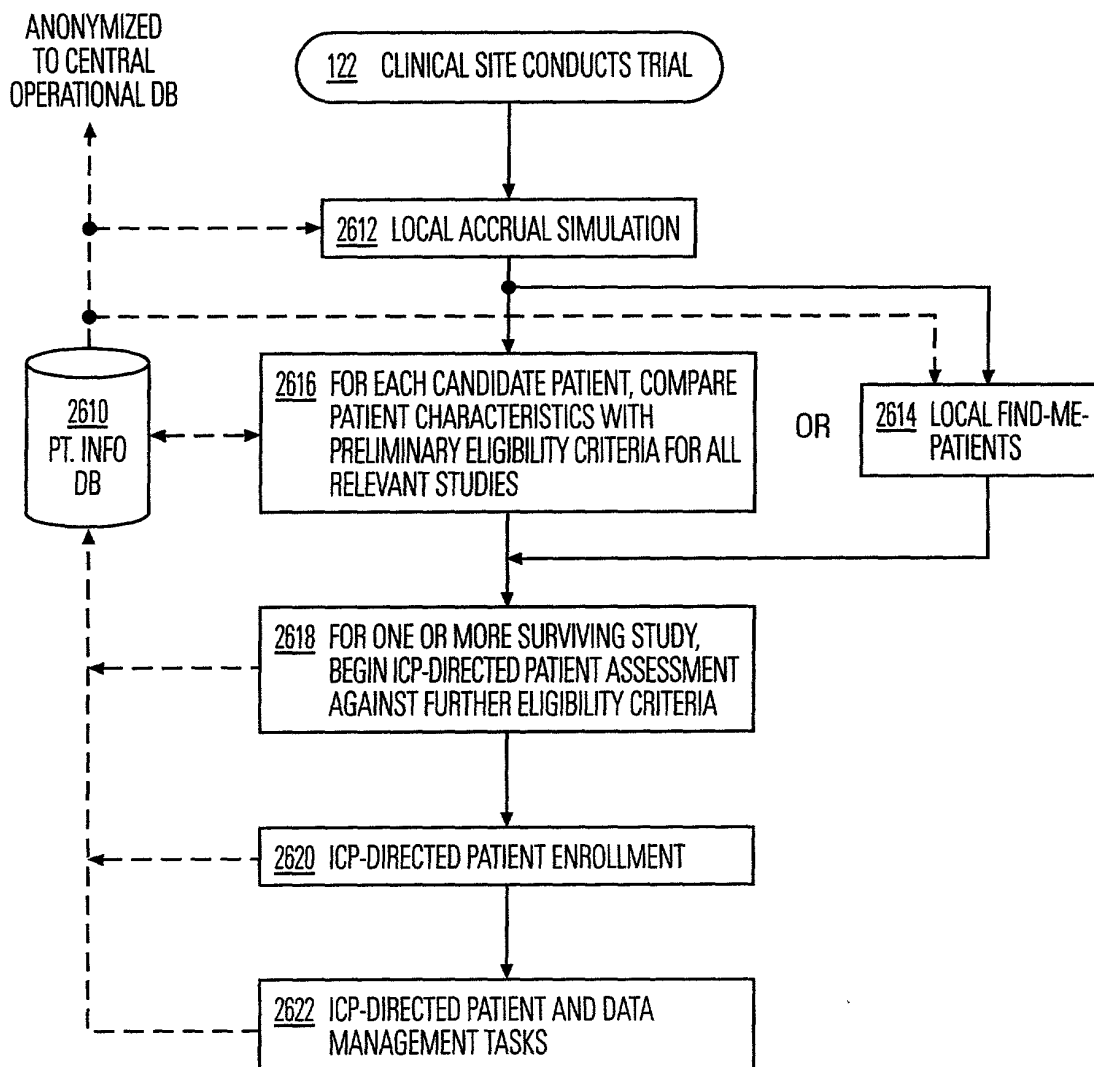


FIG. 26

27/40

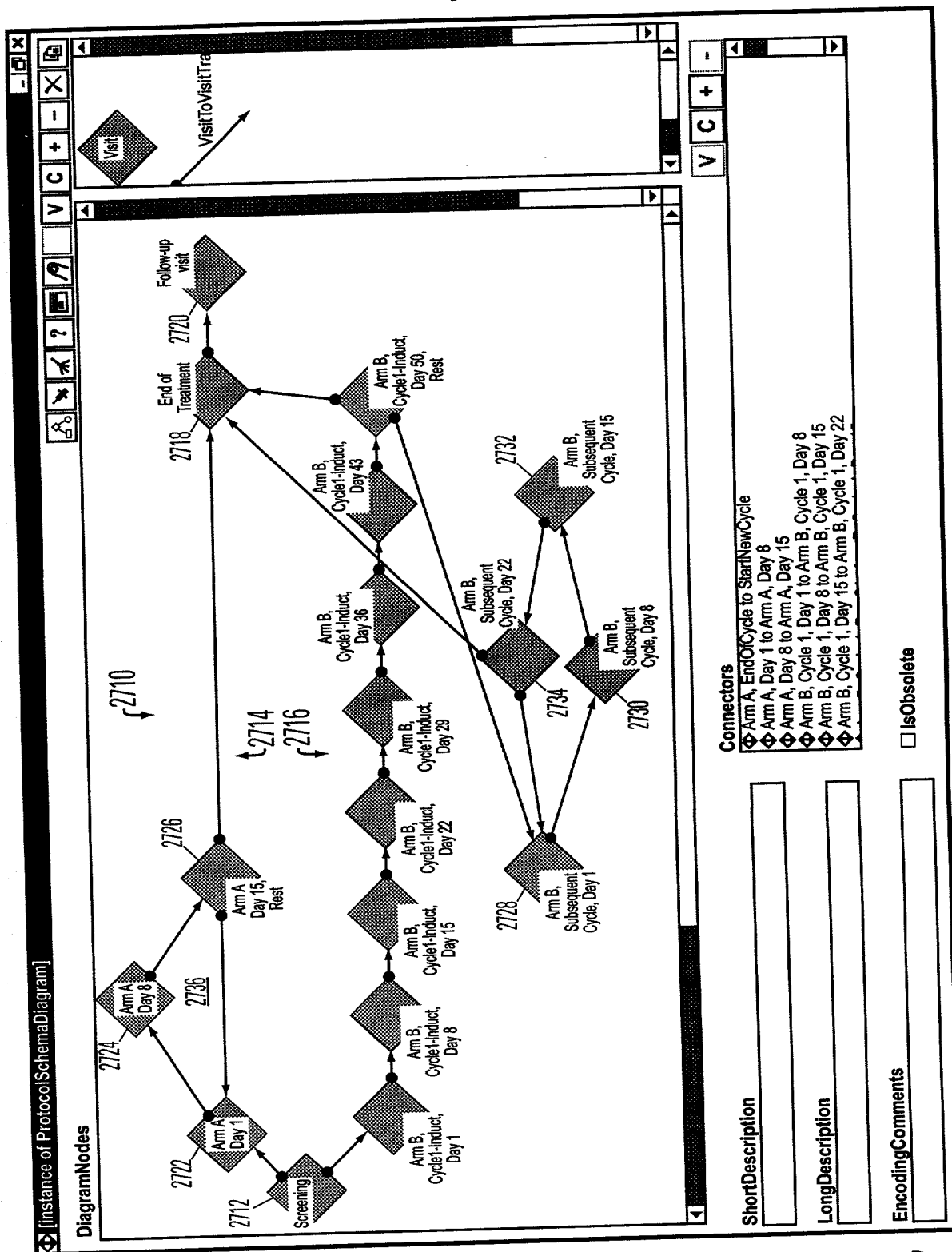


FIG. 27

28/40

Protocol Protégé-2000 [D:\Work\Sample\Protocol.ppr]

Project Edit Window Help

Classes Slots Forms Instances

Relationship: Subclass V C +

Diagram showing class hierarchy:

```

    graph TD
        THINGA[THINGA] --> SYSTEMCLASSA[SYSTEM-CLASSA]
        SYSTEMCLASSA --> Diagram_Entity[Diagram_Entity]
        Diagram_Entity --> Date[Date]
        Date --> ProtocolElementA[ProtocolElementA-1112]
        ProtocolElementA --> EligibilityCriteriaSet[EligibilityCriteriaSet-1124]
        EligibilityCriteriaSet --> EligibilityCriterion[EligibilityCriterion]
        EligibilityCriterion --> PatientManagementTask[PatientManagementTask-1130]
        PatientManagementTask --> Protocol[Protocol-1116]
        Protocol --> ProtocolSchemaDiagramM[ProtocolSchemaDiagramM-1132]
        ProtocolSchemaDiagramM --> Visit[Visit-1128]
        Visit --> VisitToVisitTransitionM[VisitToVisitTransitionM]
        VisitToVisitTransitionM --> DiseaseArea[DiseaseArea]
        DiseaseArea --> Arm[Arm-1150]
        Arm --> WeightedPath[WeightedPath-1152]
        WeightedPath --> ApplicationArea[ApplicationArea]
        ApplicationArea --> VisitCycle[VisitCycle-1154]
        VisitCycle --> DiseaseA[DiseaseA]
        DiseaseA --> DiseaseQualifiersA[DiseaseQualifiersA]
        DiseaseQualifiersA --> ModelVersion[ModelVersion]
    
```

Arm (Instance of :STANDARD-CLASS)

Name: Arm

Constraints: V C +

Documentation:

Role: Concrete

Template Slots:

| Name | Type | Cardinality | Default | Other Facets |
|------------------|----------|-------------|---------|-----------------------------|
| drillDown | Boolean | single | false | |
| encodingComments | String | single | | |
| isObsolete | Boolean | single | false | |
| longDescription | String | single | | |
| obsoleteVisits | Instance | multiple | | classes={Visit, VisitCycle} |
| shortDescription | String | single | | |
| Visits -2812 | Instance | multiple | | classes={Visit, VisitCycle} |

Superclasses: ProtocolElementA

FIG. 28

29/40

0990182 030400 204050 28102660

[instance of Arm]

ShortDescription

Arm A --2710

LongDescription

Arm A: Gemcitabine and Irinotecan HCl (CPT-11)

EncodingComments

Editorial change

Visits

V C + -

◆ Screening --2712

◆ Arm A, Day 1 --2722

◆ Arm A, Day 8 --2724

◆ Arm A, Day 15, Rest --2726

◆ End of Treatment --2718

◆ Follow-up Visit --2720

ObsoleteVisits

V C + -

☐ IsObsolete

☐ DrillDown

FIG. 29

30/40

Protocol Protégé-2000 [D:\Work\Sample\Protocol.ppt]

Project Edit Window Help

Classes Slots Forms Instances

Relationship: Subclass V C X

Relationship: C:THINGA

- C:SYSTEM-CLASS^A
- C:Diagram_Entity
- C:Date
- C:ProtocolElement^A
- C:EligibilityCriteriaSet
- C:EligibilityCriterion
- C:PatientManagementTask
- C:Protocol
- C:ProtocolSchemaDiagram^M
- C:Visit
- C:VisitToVisitTransition^M
- C:DiseaseArea
- C:Arm — 1150
- C:WeightedPath — 1152
- C:ApplicationArea
- C:VisitCycle — 1154
- C:Disease^A
- C:DiseaseQualifiers^A
- C:ModelVersion

WeightedPath (Instance of :STANDARD-CLASS)

Name: WeightedPath

Constraints: V C + -

Documentation:

Role: Concrete

Template Slots

| Name | Type | Cardinality | Default | Other Facets |
|-------------------|----------|-------------|---------|-----------------------------|
| drillDown | Boolean | single | false | |
| encodingComments | String | single | | |
| isObsolete | Boolean | single | false | |
| longDescription | String | single | | |
| obsoleteVisits | Instance | multiple | | classes={Visit, VisitCycle} |
| pathWeight — 3014 | Integer | single | 1 | |
| shortDescription | String | single | | |
| Visits — 3012 | Instance | multiple | | classes={Visit, VisitCycle} |

3010

Superclasses: C:Arm

FIG. 30

31/40

3110

[instance of WeightedPath]

| | |
|--|---|
| ShortDescription
Arm A Path | Visits
V C + -
◆ Screening → 2712
◆ Arm A Cycle → 2736
◆ End of Treatment → 2718
◆ Follow-up cycle → 2720 |
| LongDescription
 | |
| EncodingComments
 | PathWeight
1 |
| <input type="checkbox"/> IsObsolete <input type="checkbox"/> DrillDown | |

FIG. 31

32/40

Protocol Protège-2000 [D:\Work\Sample\Protocol.ppr]

Project Edit Window Help

Classes Slots Forms Instances

Relationship: Subclass V C X

VisitCycle (instance of :STANDARD-CLASS)

Name: VisitCycle

Constraints: V C +

Documentation:

Role: Concrete

Template Slots

| Name | Type | Cardinality | Default | Other Facets |
|---------------------|----------|-------------|---------|-----------------------------|
| cycleCount — 3214 | Integer | single | 1 | |
| drillDown | Boolean | single | false | |
| encodingComments | String | single | | |
| isObsolete | Boolean | single | false | |
| longDescription | String | single | | |
| shortDescription | String | single | | |
| visitInCycle — 3212 | Instance | multiple | | classes={Visit, VisitCycle} |

Superclasses: ProtocolElement^A

Relationships:

- THING^A
 - SYSTEM-CLASS^A
 - Diagram_Entity
 - Date
 - ProtocolElement^A
 - EligibilityCriteriaSet
 - EligibilityCriterion
 - PatientManagementTask
 - Protocol
 - ProtocolSchemaDiagram^M
 - Visit
 - VisitToVisitTransition^M
 - DiseaseArea
 - Arm — 1150
 - WeightedPath — 1152
 - ApplicationArea
 - VisitCycle — 1154
 - Disease^A
 - DiseaseQualifiers^A
 - ModelVersion

FIG. 32

33/40

2736

[instance of VisitCycle]

| | |
|--|---|
| ShortDescription
Arm A Cycle | VisitsInCycle
V C + -
◆ Arm A, Day 1 → 2722
◆ Arm A, Day 8 → 2724
◆ Arm A, Day 15, Rest → 2726 |
| LongDescription
 | |
| EncodingComments
 | CycleCount
3 |
| <input type="checkbox"/> DrillDown <input type="checkbox"/> IsObsolete | |

FIG. 33

34/40

Timeline Simulation Process Flow

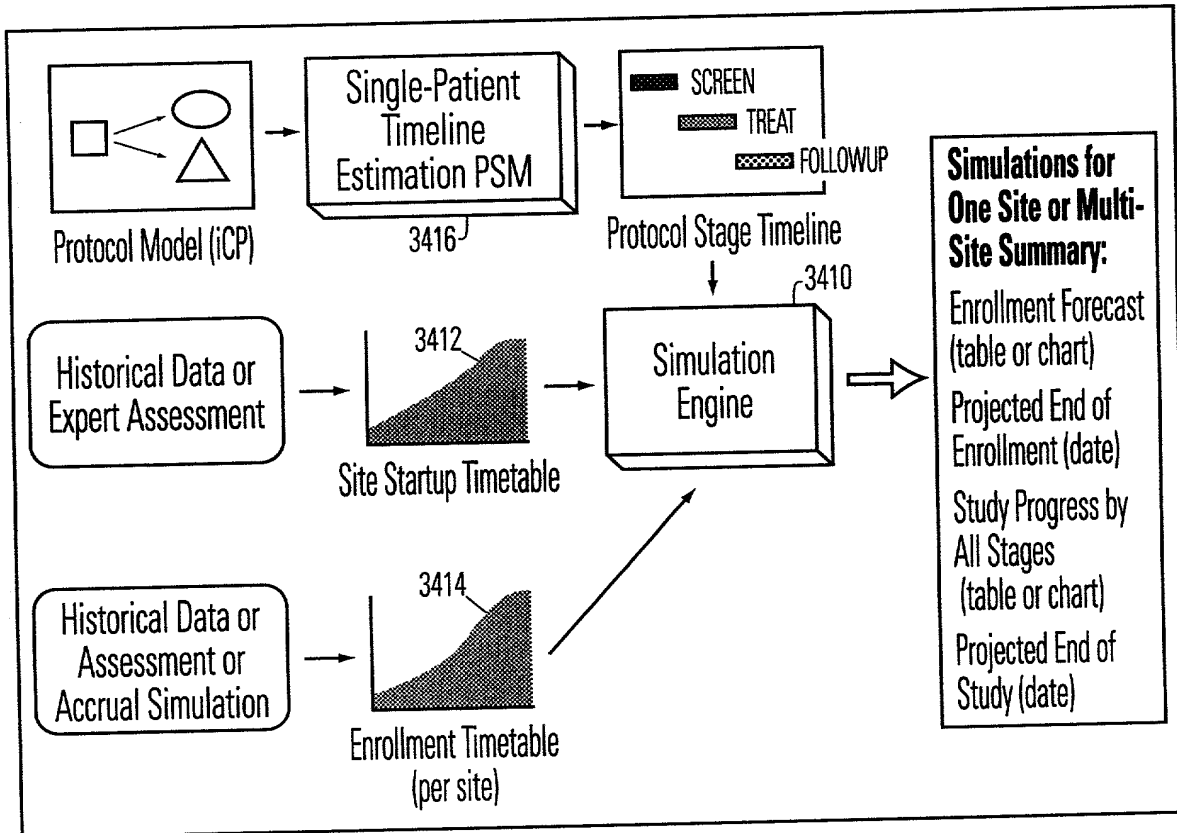


FIG. 34

35/40

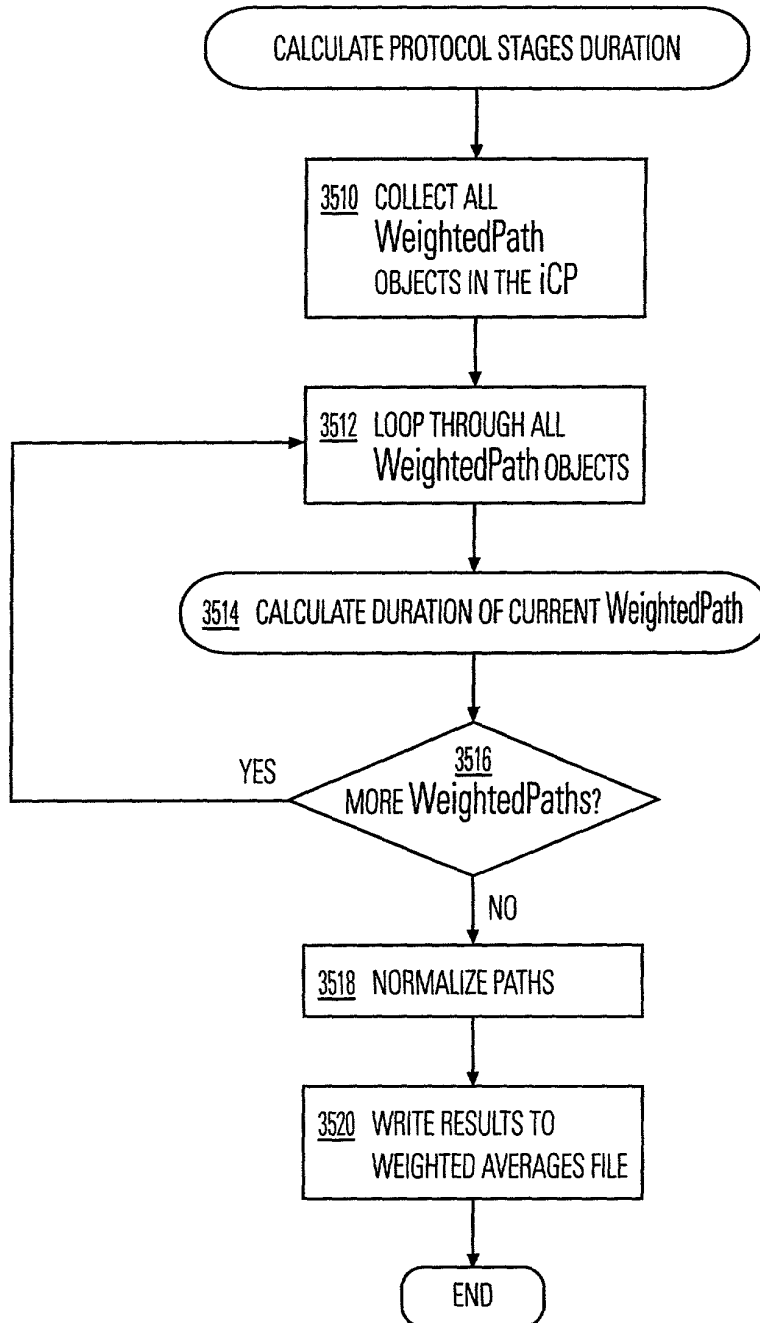


FIG. 35

36/40

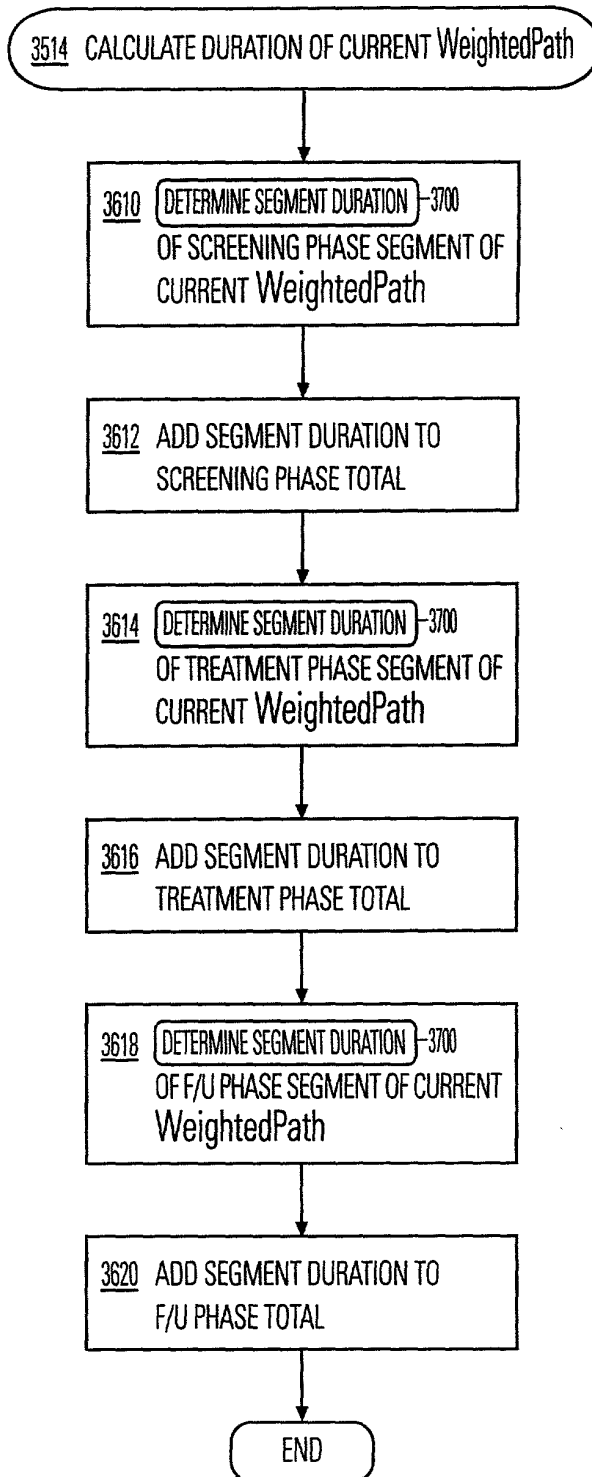


FIG. 36

37/40

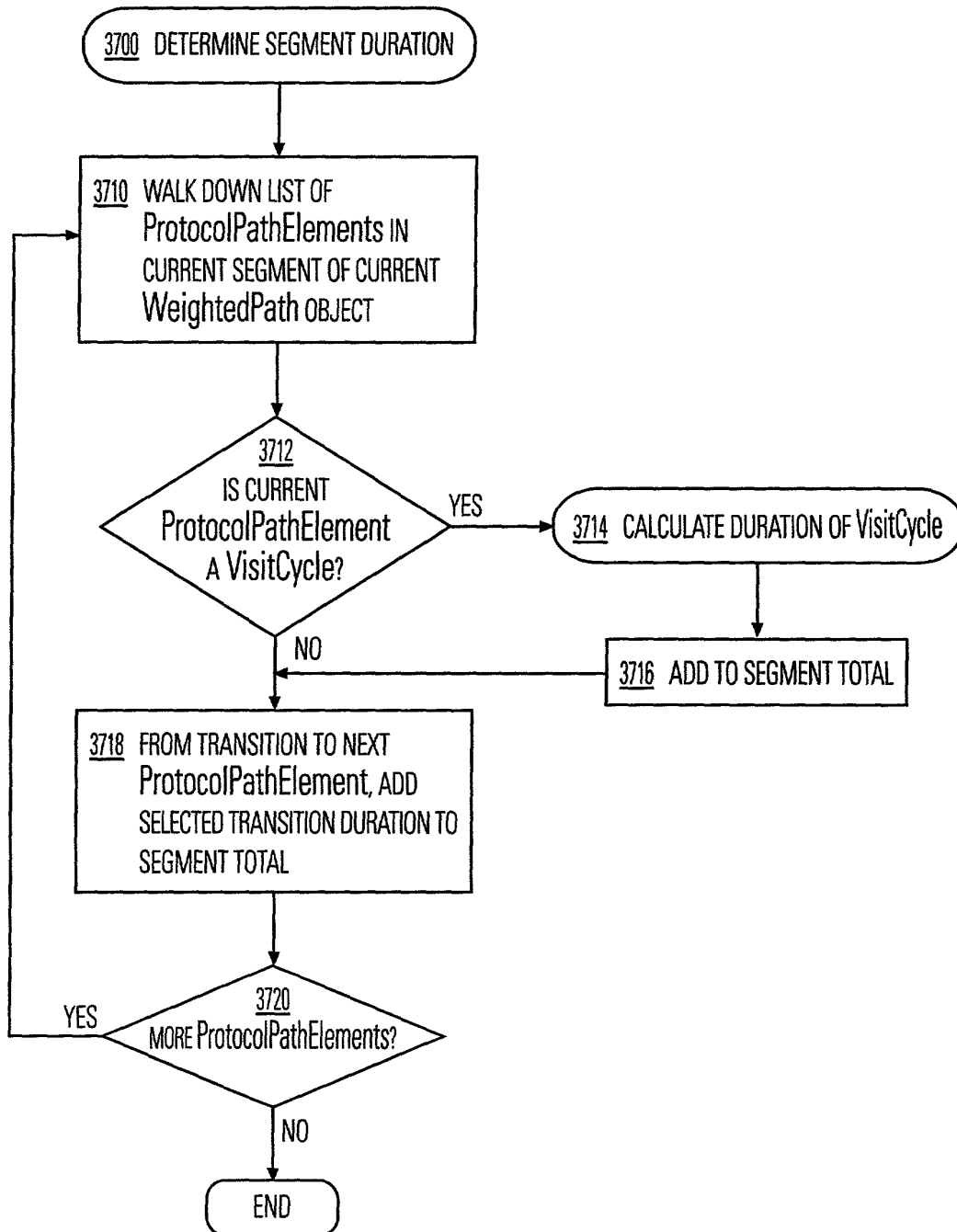


FIG. 37

38/40

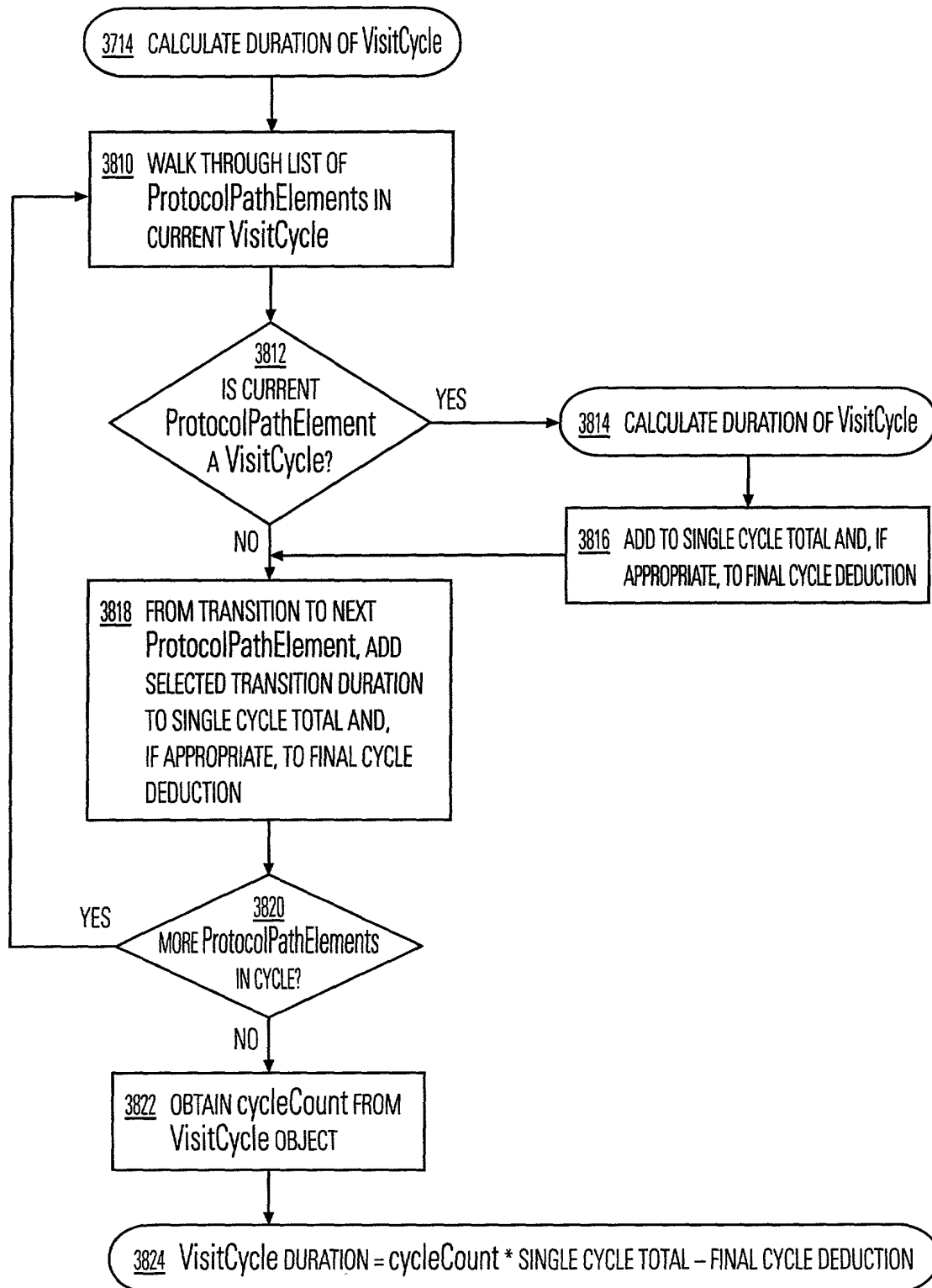
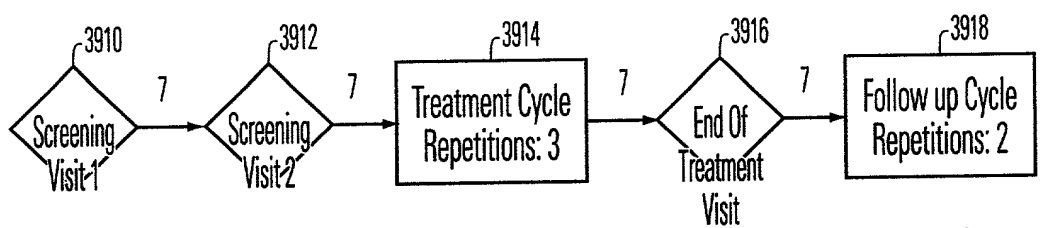
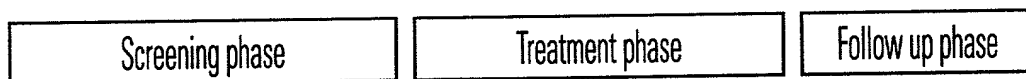


FIG. 38

39/40

Screening duration = $7 + 7 = 14$
 Treatment = $3 * (1 + 1 + 1) - 1 + 7 + 7 = 22$
 Follow up = 30



ProtocolPathElements:
 Visits: diamonds
 VisitCycles: rectangles

Expansion of VisitCycles

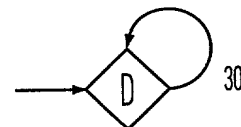
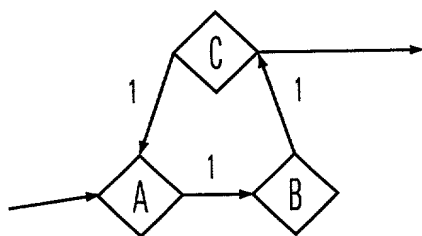
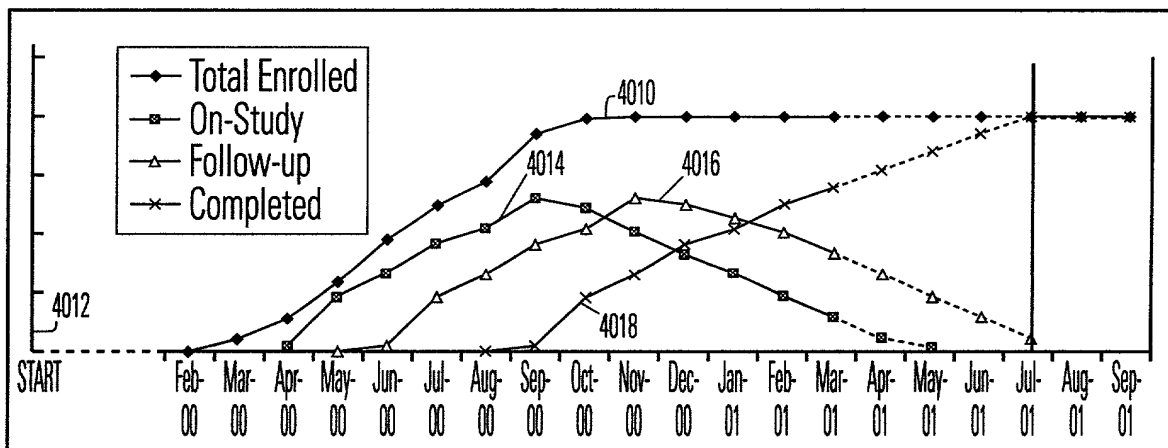


FIG. 39

40/40

Forecast Trial Completion



The last patient should complete follow-up in July 2001

FIG. 40